

FEB 18 2005

K043553

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name: Catheter, Peripheral, Atherectomy
21 CFR §870.4875, Class II
Common and Usual Name: Catheter, Peripheral, Atherectomy
Proprietary Name: SilverHawk Peripheral Plaque Excision System

Predicate Device

The ReFORM Peripheral Catheter System (K024243), currently marketed by FoxHollow Technologies, Inc. (Redwood City, CA).

Summary

This summary of Special 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The SilverHawk Peripheral Plaque Excision System is intended for atherectomy of the peripheral vasculature and is not intended for use in the coronary or carotid vasculature. The SilverHawk Peripheral Plaque Excision System consists of two major components which are packaged separately, but used together during atherectomy procedures. The two components are the SilverHawk Peripheral Catheter and SilverHawk Cutter Driver.

The SilverHawk Peripheral Plaque Excision System will be provided sterile for single-use. The catheter will be sterilized by Ethylene Oxide (ANSI/AAMI/ISO 11135), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6} . The cutter driver is sterilized by Gamma Sterilization Cycle (ANSI/AAMI/ISO 11137), providing a minimum SAL of 10^{-6} , with a minimum dose of 25kGy, using the Vmax method. The device is biocompatible per ISO-10993-1.

The SilverHawk Peripheral Plaque Excision System is substantially equivalent in material of construction, overall design, intended use, and safety and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The SilverHawk Peripheral Plaque Excision System is considered substantially equivalent to the ReFORM Peripheral Catheter System (#K024243).

Contact:

Date: December 22, 2004

Melissa Murphy
Regulatory Specialist
FoxHollow Technologies, Inc.
300 Saginaw Drive
Redwood City, CA 94063
(650) 421-8579



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

FoxHollow Technologies, Inc.
c/o Ms. Melissa Murphy
Regulatory Specialist
300 Saginaw Drive
Redwood City, CA 94063

Re: K043553

Trade Name: Catheter, Peripheral, Atherectomy
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: December 22, 2004
Received: December 27, 2004

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043553

Device Name: SilverHawk Peripheral Plaque Excision System

Indications For Use:

The SilverHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The catheter is not intended for use in the coronary or carotid vasculature.

The intended use of the SilverHawk Peripheral Plaque Excision System is identical to the approved indication for the ReForm Peripheral Catheter System which was found to be substantially equivalent to the Simpson Peripheral Atherocath (K871011, K874706, K881088 and K883346). Both the SilverHawk Peripheral Plaque Excision System and the ReForm Peripheral Catheter System are designed for atherectomy of the peripheral vasculature and *neither* device is intended for use in the coronary or carotid vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) number K043553